Remarks

Claims 14-17, 32-37, and 40-47 are pending in the application following entry of this Amendment. Claims 14-17 and 42-47 stand withdrawn. Claims 35, 40, and 41 have been amended. Claim 32 is the only independent claim pending and not withdrawn.

No new matter is added by the amendments made herein. Support for the amendments to the claims is found in the specification as follows.

The amendment to claim 35 merely corrects a typographical error (inadvertent capitalization of "Claim").

Claims 40 and 41 were amended to alter the name given the composition recited in claim 40. Whether or not that composition is designated a "pharmaceutical composition," it is clearly a "composition" and the claim is supported as previously cited.

Each of the Examiner's objections or rejections is addressed below in the order they were presented in the Office Action.

Objection to Specification

The Examiner objected to the reference to the related provisional application. The corresponding paragraph on page 1 of the specification has been amended in a manner that the Applicant believes renders the Examiner's objection moot. The Examiner is requested to reconsider and withdraw the rejection.

Rejection Pursuant to 35 U.S.C. § 101

The Examiner rejects all of the pending, non-withdrawn claims pursuant to 35 U.S.C. § 101. In the Examiner's view, the antibody recited in these claims does not have a substantial utility. The Examiner asserts that the specification does not adequately prove the involvement of MCT-1 protein in cell cycle regulation or in cancer, and that recognition that MCT-1 protein is involved in protein-protein interactions is not a sufficiently substantial indication of utility for the claimed antibody.

The Applicants do not doubt that the Examiner understands that the specification need only identify a specific, substantial utility for subject matter that is claimed, and that definitive proof of that utility need not be set forth in detail. The Applicant respectfully contends that the involvement of MCT-1 protein in cell cycle regulation and in cancer has been conclusively demonstrated in the published literature. For example, enclosed with this Amendment are two published papers and an abstract of a third published paper. Each of the two published papers (Levenson et al., 2005, Cancer Res. 65:10651-10656 and Shi et al., 2003, Blood, 102:297-302) demonstrate that MCT-1 is overexpressed in cancerous cells. The enclosed abstract (Hsu et al., 2005, Oncogene 24:4956-4964, abstract only) as well as the Levenson paper demonstrate the accepted role of MCT-1 in cell cycle regulation (including apoptosis).

The Applicants respectfully contend that identification of these activities in the specification is not a mere "invitation to experiment" (as the Examiner suggests at page 12 of the Office Action), but is instead identification of a substantial, specific, practical utility for the antibodies that are recited in the claims. The Applicants respectfully request that the Examiner reconsider the rejection of all pending, non-withdrawn claims pursuant to 35 U.S.C. § 101 in light of the information presented above and withdraw that rejection.

Rejections Pursuant to 35 U.S.C. § 112, First Paragraph

In item 7 of the Office Action, the Examiner rejects all of the pending, non-withdrawn claims pursuant to the enablement requirement of 35 U.S.C. § 112, first paragraph. In the Examiner's view, the specification's purported failure to identify a substantial utility for the claimed antibodies would preclude a skilled artisan from being enabled by the specification to make use of those antibodies. The Applicants believe that the information presented in connection with the Examiner's rejection pursuant to 35 U.S.C. § 101 is equally applicable to this rejection, and that this rejection should be withdrawn for the same reasons presented in connection with that rejection.

In item 8 of the Office Action, the Examiner indicates that claims 40 and 41 stand rejected pursuant to the enablement requirement of 35 U.S.C. § 112, first paragraph. In the

Examiner's view, recitation in claim 40 of a "pharmaceutical" composition implies that the composition is intended only for therapeutic use and the specification does not enable therapy. The Applicants respectfully reply that the question of whether therapy is enabled by the specification is not raised by the pending claims. Because claim 40 is not intended to encompass only therapeutic compositions (i.e., but rather, compositions including a "cell-compatible" or "tissue-compatible" carrier, regardless of the use to which those compositions are put), the Applicant has deleted the word "pharmaceutical" from the preamble of claim 40 and from claim 41. The Applicant respectfully believes that this alteration renders the Examiner's rejection moot and requests withdrawal of this rejection.

(The Office Action does not appear to include an item #9.)

In items 10-12 of the Office Action, the Examiner rejects claims 33-35 pursuant to the written description requirement of 35 U.S.C. § 112, first paragraph. In the Examiner's view, the portions of the specification previously cited by the Applicant as supporting claims 33-35 do not disclose the "ten consecutive amino acid residues of homologous residues 1-114 of SEQ ID NOs: 2 and 8" or the recitation of ten or twenty consecutive amino acid residues. The Applicant directs the Examiner's attention to page 17, lines 19-20, at which the homologous region 1-114 of SEQ ID NOs: 2 and 8 is disclosed, and to claim 14 and page 17, lines 16-19 of the specification as filed, which recites at least ten or twenty consecutive residues of such sequence. The Applicant respectfully contends that these disclosures, together with those previously cited, constitute an adequate written description of the subject matter recited in claims 33-35. Reconsideration and withdrawal of the Examiner's rejections in items 10-12 are respectfully requested.

In item 13 of the Office Action, the Examiners rejects claims 40 and 41 pursuant to the written description requirement of 35 U.S.C. § 112, first paragraph. The Examiner interprets the phrase "pharmaceutical composition" in the preamble of claim 40 (as repeated in claim 41) to imply that the claimed composition has therapeutic efficacy. In order to eliminate the basis for

that interpretation, the Applicant has amended claim 40 (and the corresponding portion of claim 41) to remove "pharmaceutical" from the claims. As amended, the claims merely recite a "composition" including the antibody of claim 32 in a pharmaceutically-acceptable carrier. The Applicants respectfully contend that no therapeutic efficacy of this composition is recited or implied in the amended claims. For this reason, the Applicant believes that the Examiner's rejection of claims 40 and 41 is moot and request reconsideration and withdrawal of that rejection.

In item 14 of the Office Action, the Examiner rejects claims 32, 36, 37, 40, and 41 pursuant to the definiteness requirement of the second paragraph of 35 U.S.C. § 112. In the Examiner's view, the identifier "MCT-1" does not adequately identify the polypeptide to which the claimed antibodies bind. The Applicant respectfully believes that the specification clearly identifies MCT-1 as the polypeptide having the amino acid sequence SEQ ID NO: 8 (see, e.g., the legend for Figure 5B at page 6, lines 13-14, of the specification). The Applicant therefore does not believe that there is any indefiniteness regarding the entity to which "MCT-1" applies. The Applicants respectfully request that the Examiner reconsider this rejection in light of this information and withdraw that rejection.

In item 15 of the Office Action, the Examiner rejects claims 33-35 pursuant to the definiteness requirement of the second paragraph of 35 U.S.C. § 112. In the Examiner's view, these claims do not clearly define the "portion" of MCT-1 to which the claimed antibody binds. The Applicant respectfully believes that these claims are clear on their face. Claim 32 (from which each of these claims depends) recites that the claimed antibody specifically binds with "a portion" of MCT-1 (i.e., any portion to which an antibody can bind). Each of claims 33-35 recites a more particular characteristic of the claimed antibody -- i.e., that it binds with an epitope present in a region including certain consecutive amino acid residues (i.e., rather than, for example, an epitope which includes residues from widely-spaced portions of the MCT-1 amino acid sequence, such as different portions of the MCT-1 polypeptide that are brought into close association as a result of protein secondary or tertiary structure, for example). The

Applicant respectfully believes that the meaning of each of claims 33-35 is clear to a skilled artisan in this field and that no modification of these claims is required in order to comply with the definiteness requirement of 35 U.S.C. § 112. The Examiner is respectfully requested to reconsider this rejection in light of this clarification and to withdraw this rejection.

Summary

The Applicants respectfully contend that each of claims 32-37, 40, and 41 is in condition for allowance. The Examiner is requested to issue a Notice of Allowance at the earliest possible time.

Respectfully submitted,

Ronald B. GARTENHAUS

7 February 2007
(Date)

By: _____

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